K092572

SPIDENT Co., Ltd.
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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

Date: July 22, 2009

AUG 2 6 2009

1. Company and Correspondent making the submission:

	Company
Name	SPIDENT Co., Ltd.
Address	#312, 151B-6L, NamdongKongDan, Incheon, Korea 405-821
Phone	+82(32)819-4570
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Contact	I. S. Whang

2. Device:
   Proprietary Name – Core · it Dual
   Common Name – Core Build up Resin
   Classification Name – Tooth shade resin material

3. Predicate Device:
   LuxaCore/ LuxaCore Dual, K012307

4. Classifications Names & Citations:
   EBF, 872.3690

5. Description:
   The Core·it Dual is a dual-cured composite resin designed for the fabrication of core build-ups & build-up fillings. It has the characteristics of good depth of polymerization, high compressive strength, and radiopaque. It has two shades (Blue, yellow).

   The Core · it Dual is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. It is substantially equivalent in design, function and intended use to the predicate devices.

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6. Indication for use:

The principal use for Core-it Dual is as a core material either with adhesives or with pins or posts.

Core-it Dual can also be used for:

- Luting of abutments to dentures
- Splinting of teeth in combination with wires, Kevlar or Ribbond-type materials
- Repair material for provisionals
- Bite registration material.
- Build up material for plastic bite rails (occlusal individualisation).
- Cement for pins and posts
- Semipermanent restorative material (e.g., in childrens' teeth)

7. Review:

The Core-it Dual has the similar device characteristics as the predicate device, the LuxaCore Dual; intended use, material, chemical composition, design and use concept are similar.

The Core-it Dual has the similar mechanical properties as the predicate device; compressive strength, flexural strength, flow thickness, wear, polymerization shrinkage and thermal expansion coefficience.

The Core-it Dual has been subjected to extensive safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the US regulations and ISO 4049.

Based on the comparison of intended use and technical features, the Core-it Dual is substantially equivalent to the predicate devices.

8. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, FDA's "Guidance for the Preparation of Premarket notifications for Dental Composite" and based on the information provided in this premarket notification. SPIDENT Co., Ltd. concludes that the Core-it Dual is safe and effective and substantially equivalent to predicate devices as described herein.

9. SPIDENT Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Spident Company, Limited
C/O Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Incorporated
Laboratory and Testing
2600 NW Lake Road
Camas, Washington 98607-9526

AUG 2 6 2009

Re: K092572
Trade/Device Name: Core·it Dual
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: July 29, 2009
Received: August 21, 2009

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/Reporta Problem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K 092572

Device Name: Core·it Dual

Indication for use:

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Core·it Dual can also be used for:

- Luting of abutments to dentures
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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Per 21CFR801 Subpart D) (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Mulay for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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